REMARKS:

Claims 12-17 are in the case and presented for consideration.

Claim 12 has been amended to further distinguish the invention claimed in the present application over the cited prior art.

In claim 12, the term "monolithic" has been replaced with "plastic viscous". Support for this amendment can be found throughout the specification, particularly on page 5, lines 7-10 and page 12, lines 1-2 of the specification.

Additionally, the claim 12 has been amended to read "... antitumor agent being homogeneously distributed in [[and]] a carrier ...." Support for this amendment can be found throughout the specification, particularly on page 11, lines 31-34

CLAIM REJECTION UNDER 35 U.S.C. §112

Claim 12 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

As mentioned above, the term "monolithic" in claim 12 has been replaced with "plastic viscous". Therefore, claim 12 is believed to fully comply with the written description requirement of 35 U.S.C. 112, first paragraph.

FIRST REJECTION UNDER 35 U.S.C. §103(a)

Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hampl et al. (International Journal of Pharmaceutics 144 (1996) 107-114) in view of Chen et al. (J. Microencapsulation, 1999, Vol. 16, No.5, 551-563).

Applicants respectfully traverse the Office's rejections that the claims of the subject application are obvious in view of the cited prior art.

The only thing which might be obvious from a combination of Hampl and Chen is that an antitumor agent can be encapsulated in microshperes which have polymer emulsifiers and residual solvents incorporated into their surface sheets.

The active matter in the present invention is directly and without any barrier scattered, i.e., homogeneously distributed, in a carrier (biodegradable oligoester). In addition, the invention claimed in currently amended claim 12 is a plastic and viscous system, i.e., a non-particulate system.

By contrast, the microspheres of Hampl and Chen represent a particle structure in which the individual fractions of active matter, represented by each individual microsphere, are separated from each other as well as the carrier. This is true irrespective of whether or not the microspheres are encompassed in a solution. In addition, this represents a significant structural difference which effects the release of active matter in ways which are neither disclosed nor suggested in Hampl or Chen. Additionally, it is important to note that the effects of said structural difference are also not disclosed or suggested in United States Patent 5,783,205 to Berggren et al. ("Berggren").

The system claimed in currently amended claim 12 is recognized to swell and degrade by the hydrolysis of the ester bonds which produces both hydroxyl and carboxyl groups. The acid degradation products catalyze further degradation of the system. Such an autocatalytic impact of the degradation products on acid hydrolysis is influenced by their stay in the oligoester system. The stay or dwell time of the degradation products in the system is completely dependent on the size of the system.

Therefore, although each individual microsphere of the systems disclosed in Hampl and Chen are single units, due to their very small size as well as their separated arrangement in the system, they cannot achieve the above described delivery, either individually or as a system. Instead the hydrolysis of these microsphere systems proceeds without the catalytic effect of the above-mentioned degradation products. Thus, in Hampl and Chen the release of active matter is influenced to a greater degree by their physico-chemical properties, such as solubility, distribution coefficient, sorption, and ionisation. The claimed invention thus has characteristics that are improved and different over the characteristics that would be expected from any obvious combination of the references under 35 U.S.C. 103 as interpreted by *KSR v. Teleflex*.

Therefore, a person of ordinary skill in the art would not find the claimed antitumor agent which is homogeneously distributed in a carrier and which has the sophisticated release mechanism described above, obvious in view of the combination of Hampl and Chen.

SECOND REJECTION UNDER 35 U.S.C. §103(a)

Claims 13-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hampl et al. (International Journal of Pharmaceutics 144 (1996) 107-114) in view of Chen et al. (J. Microencapsulation, 1999, Vol. 16, No.5, 551-563) and further in view of Berggren.

Applicants respectfully traverse the Office's rejections that the claims of the subject application are obvious in view of the cited prior art.

Because claim 12 is not obvious in view of the cited prior art, claims 13 through 17, which all depend from claim 12, are also nonobvious.

In addition, with respect to claim 17, the cited teaching in Berggren, i.e., "matrix material is heated to soften the material to a point where it becomes flowable and can be delivered at a physiologically compatible elevated temperature into a biological pocket[,]" should not be applied in an obviousness rejection since it involves the administration rather than the preparation of the concerned composition.

Accordingly, the application and claims are believed to be in condition for allowance, and favorable action is respectfully requested.

No new matter has been added.

If any issues remain, the Examiner is respectfully invited to contact the undersigned at the number below, to advance the application to allowance.

Respectfully submitted,
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